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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,962	09/29/2006	Tomoki Todo	042715-5023	6716
9629 7590 05/24/2010 MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004				
EXAMINER				
HAMA, JOANNE				
ART UNIT		PAPER NUMBER		
1632				
MAIL DATE		DELIVERY MODE		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/594,962

**Applicant(s)**

TODO ET AL.

**Examiner**

JOANNE HAMA

**Art Unit**

1632

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 and 16-22 is/are pending in the application.
- 4a) Of the above claim(s) 12-14, 16-20 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB-06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of a virus comprising a nucleotide sequence that encodes a target protein in the reply filed on February 28, 2010 is acknowledged.

Claim 22 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 28, 2010.

As indicated in the Office Action of June 18, 2009, claims 12-14, 16-20 are withdrawn as being drawn to nonelected inventions.

Claim 15 is cancelled.

Claims 1-11, 21, drawn to a method for constructing recombinant herpes simplex virus, is under consideration.

### ***Information Disclosure Statement***

Applicant filed an Information Disclosure Statement (IDS) on January 27, 2010. The IDS has been considered. It is noted that US 2002/110543 has been lined through and indicated as a duplicate ("dup") because it has already been cited on the 892 filed July 28, 2008. Also, the abstract by Saeki et al., 2001 has been lined through and indicated as a duplicate ("dup") as it has already been cited in Applicant's IDS filed September 29, 2006.

### ***New/Maintained Rejections***

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 remain rejected and new claim 21 is newly rejected under 35 U.S.C. 103(a) as being unpatentable over Chiocca et al., US Patent Application Publication US 2002/0110543 A1, published August 15, 2002, previously cited, in view of Breakefield et al., US Patent, 6,573,090, patented June 3, 2003, Saeki et al., 2001, Molecular Therapy, 3: 591-60, Buchholz et al., 2001, Nature Biotechnology, 19: 1047-1052, previously cited, Krisky et al., 1998, Gene Therapy, 5: 1517-1530, previously cited, Todo et al., 2001, Cancer Research 61: 153-161, Bennett et al., 2001, Annals of Surgery, 233: 819-826, for reasons of record July 28, 2008, June 18, 2009, November 25, 2009.

Applicant's arguments filed December 16, 2009 have been fully considered but they are not persuasive.

Applicant indicates that Breakefield et al. teaches that BAC clones that is more than 150 kb in length cannot package into viral capsids. Thus, according to the Office Action, an artisan would recognize that any genetic construct that is more than 150kb would not be able to package in a capsid and thus could not be used to generate recombinant herpes. Applicant indicates that a recombinant herpes simplex virus containing a genetic construct that is greater than 150kb in length was made

(Applicant's response, pages 6-7). In response, this is not persuasive. Breakefield et al. was cited to illustrate that at the time of filing, artisans exploited the fact that because DNA larger than 150kb could not be packaged into HSV virions, artisans intentionally made vectors more than 150kb in size and would only allow HSV genome to be packaged and propagated after removal of unwanted DNA sequence (e.g. the BAC vector backbone can have deleterious effects on the HSV virus and an artisan would design the recombination sites such that these regions could be deleted), see Kuroda et al., 2006, BMC Biotechnology, 6: 40, page 2 of printout, 1<sup>st</sup> col., 2<sup>nd</sup> parag. to 2<sup>nd</sup> col. 1<sup>st</sup> parag.). With regard to the vector being at least 150kb (claim 1 step 3), Chiocca et al. teach that the vector used to make virion in the Vero cell is 152kb, (Chiocca et al., Figure 7).

Thus, the claims remain rejected.

### ***Conclusion***

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Mondays, Tuesdays, Thursdays, and Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Joanne Hama/  
Primary Examiner  
Art Unit 1632